

REMARKS

Reconsideration is requested.

An interview is requested with the Examiner prior to issuance of a further Action by the Examiner. The Examiner is requested to contact the undersigned to arrange a time for the interview which is convenient to the Examiner's schedule. The interview is requested so that any outstanding issues can be discussed and hopefully resolved prior to the Examiner's next Action in this application which has been pending for over six (6) years.

The Examiner is requested to provide a complete PTO 892 Forms, which include the title of each cited Non-Patent Document.

Specifically, the PTO 892 Forms "Part of Paper No. 05012006" and "Part of Paper No. 11182004" fails to include the title of each Non-Patent Document.

The Examiner will appreciate that MPEP § 707.05(e) provides as follows:

707.05(e) Data Used in Citing References [R-2]

37 CFR 1.104(d) (see also MPEP § 707.05 and § 901.05(a)) requires the examiner to provide certain data when citing references. The examiner should provide the citations on the "Notice of References Cited" form PTO-892 (copy at MPEP § 707.05). ...

III. < PUBLICATIONS

In citing a publication, sufficient information should be given to determine the identity and facilitate the location of the publication. ...

In citing periodicals, information sufficient to identify the article includes the author(s) and title of the article and the title, volume number issue number, date, and pages of the periodical.

See
http://www.uspto.gov/web/offices/pac/mpep/documents/0700_707_05_e.htm#sect707.05e (August 29, 2007) (Emphasis added.)

The Examiner is requested to provide a new PTO 892 Forms which include the information required by the MPEP, such as is described in the above-quoted passage.

For completeness, the applicants note that the Examiner has acknowledged consideration of "Ye et al, *Biochimica et Biophysica Acta* 1339 (1997) pp 39-52" on the PTO 1449 Form received with the Office Action dated May 16, 2005. The title to the considered document is as follows: "Cloning and sequencing of a cDNA for firefly luciferase from *Photinus Pennsylvanica*". The Examiner is requested to additionally list the reference on a PTO 892 Form, with the title, if believed by the Examiner to be required.

The specification has been amended to include the attached new Sequence Listing. The attached paper and computer readable copies of the Sequence Listing are the same. No new matter has been added.

Specifically, SEQ ID NO:38 is the same as SEQ ID NO:37 of the previous Sequence Listing except for the inclusion of "Xaa" at position 214 and a definition of Xaa as any amino acid. Support for SEQ ID NO:38 can be found, for example, on page 4, lines 15-19, of the originally-filed specification.

SEQ ID NO:39 is the same as SEQ ID NO:37 of the previous Sequence Listing except for the inclusion of "Xaa" at position 214 and a definition of Xaa as cysteine, alanine or asparagine. Support for SEQ ID NO:39 can be found, for example, on page

6, lines 19-33, page 7, lines 31-36, and in Example 7 on pages 22-23, of the originally-filed specification.

SEQ ID NO:40 is the same as SEQ ID NO:37 of the previous Sequence Listing except for the inclusion of "Xaa" at position 214 and a definition of Xaa as alanine and inclusion of "Xaa" at position 354 as a lysine. Support for SEQ ID NO:40 can be found, for example, on page 6, lines 19-33, and page 7, lines 31-36, page 11, lines 26-33, and in Example 6 on page 21, with reference to Figures 3B and 3F, of the originally-filed specification.

SEQ ID NO:41 is the same as SEQ ID NO:37 of the previous Sequence Listing except for the inclusion of "Xaa" at position 214 and a definition of Xaa as alanine and inclusion of "Xaa" at position 354 as a lysine and inclusion of "Xaa" at position 232 as a alanine. Support for SEQ ID NO:41 can be found, for example, on page 6, line 19 through page 7, line 2, and page 7, lines 31-36, page 8, lines 20-23, page 11, lines 26-33, and in Example 3, page 19, with reference to Figure 2, of the originally-filed specification.

SEQ ID NO:42 is the same as SEQ ID NO:37 of the previous Sequence Listing except for the inclusion of "Xaa" at position 214 and a definition of Xaa as alanine and inclusion of "Xaa" at position 354 as a lysine and inclusion of "Xaa" at position 232 as a alanine and inclusion of "Xaa" at position 215 as leucine. Support for SEQ ID NO:42 can be found, for example, on page 6, line 19 through page 7, line 2, and page 7, lines 31-36, page 8, lines 20-23, page 11, lines 26-33, page 11, line 36 through page 12, line 3, and in Example 6 on page 21, with reference to Figures 3D and 3H, of the originally-filed specification.

No new matter has been added.

The claims has been amended to include claims 106-162 which define a recombinant protein comprising a variant form of SEQ ID NO:38 which is the same as SEQ ID NO:38 but for difference of no more than 29 amino acids at positions other than position 214 of SEQ ID NO:38. Support for the definition of the variant form of SEQ ID NO:38 in claim 106 can be found, for example, in the above-noted passages which describe SEQ ID NO:38 as well as the description spanning pages 3-4 of the specification. Specifically, the applicants described their invention as including recombinant proteins containing substantially the sequence of wild-type *Photinus pyralis*, for example, wherein no more than 30 amino acids have been engineered to be different to that of the wild type enzyme. As SEQ ID NO:38 contains the difference at position 214 as compared to the wild type sequence, as described above, then one of ordinary skill in the art will appreciate the applicants specification to describe, for example, the additional inclusion of no more than 29 (i.e., 30-1) other amino acid changes as compared to the wild type sequence (e.g., of SEQ ID NO:37).

Similar support can be detailed for the recitations of 28, 27 and 26 amino acid differences in claims 109-111.

The Examiner will appreciate that the recitations of the enumerated positions in the "other than positions" recitations of claims 109-111 ensure that the different amino acids will not define the amino acids in the enumerated positions as the wild type amino acids. The claims are definite and supported by an adequate written description.

The Examiner is also requested to appreciate that as SEQ ID NO:37 is a sequence of 550 amino acids, a change of no more than 30 amino acids of SEQ ID

NO:37 defines a variant sequence which is greater than 95% (i.e., $(520/550) \times 100 = 95\%$) identical to the wild type sequence. The Examiner defined an "identity" comparison as allowing "for no mismatches". See page 8 of the Office Action dated April 3, 2007. The description of the invention in the paragraph spanning pages 3-4 of the specification is believed to be one of "identity" as defined by the Examiner.

Claims 106-120 therefore are believed to define an amino acid sequence variation of no less than 95% sequence identity to the wild-type sequence. The differences noted in the facts presented by consideration of the now-canceled claims as compared to Example 14 of the Written Description Guidelines are not believed to exist with the newly presented claims. See for example, pages 6-9 of the Office Action dated April 3, 2007.

The claims additionally include claims 121-162 which define recombinant proteins which require or relate to the amino acid sequences of SEQ ID NOs: 38-42 and are supported, for example, by the above-noted passages of the specification.

The applicants note that the specification describes in the following passages, for example, that the recombinant proteins of the applicants invention include embodiments containing more than a single mutation as compared to wild-type sequences: page 2, lines 20-25; page 3, lines 25-29 et seq.; page 3, line 31 through page 4, line 7; page 4, lines 15-17 et seq.; page 6, lines 24-28 et seq.; page 11, lines 25-34; page 12, lines 5-15; page 12, lines 17-19; and page 12, line 21 through page 14, line 17.

The objection to claim 86 is moot in view of the above.

The Rule 75 objection of claim 105 is moot.

The Section 112, second paragraph, rejection of claims 87, 89 and 104-105 is moot in view of the above. For completeness, the applicants note the now-canceled recitation of 550 is supported by the 550 amino acid length of the wild-type sequence of SEQ ID NO:37, which is believed to be described throughout the specification.

The Examiner's comment regarding the citation of support for amendments is noted and the applicants have attempted above to provide the same. The Examiner is requested to contact the undersigned, preferably by telephone, in the event anything further is required in this regard.

The dependent claims are believed to further define the subject matter of the claims from which they depend.

The claims are believed to be definite.

The Section 112, first paragraph "written description", rejection of claim 86-105 is moot in view of the above. The claims are believed to be supported by an adequate written description and consideration of the above in this regard is requested.

The Section 112, first paragraph "enablement", rejection of claims 86-105 is moot in view of the above. The applicants submit that one of ordinary skill in the art will be able to make and use the claimed invention, without undue experimentation.

The provisional obvious-type double patenting rejection of claims 86-105 over claims 1-4, 6-10, 14-19, 21, 24-26 and 29-37 of copending application Serial No. 10/111,723 is moot.

The undersigned has been advised by the overseas agent for the Assignee that application Serial No. 10/111,723 was filed as a U.S. national phase application on 26

April 2002 from WO01/31028 which has an International filing date of 26 October 2000, each of which dates is later the corresponding filing dates of the present application.

The Examiner will appreciate that MPEP § 804 provides the following:

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.

The undersigned has been further advised that the pending claims of application Serial No. 10/111,723 refer or relate to SEQ ID NO: 2 of that application, which is understood to be the amino acid sequence of a luciferase from *P. pyralis* which differs from the wild type sequence by virtue of the following mutations: 214C, 354K and 357F, while SEQ ID NO: 1 of that application is a nucleotide sequence encoding the luciferase of SEQ ID NO: 2 of that application.

The Section 102 and Section 103 rejections of 87-88 over Wood (U.S. Patent Application Publication No. 2003/0068801), are moot. The claims are submitted to be patentable over the cited art.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned, preferably by telephone, in the event anything further is required to place the application in condition for allowance.

SQUIRRELL et al.
Appl. No. 09/763,824
August 31, 2007
Amendment

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /B. J. Sadoff/
 B. J. Sadoff
 Reg. No. 36,663

BJS:
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100